

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
BEAUMONT DIVISION

MARK A. BARRY, M.D.,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

Civil Action No. 1:14-cv-104

**JUDGE RON CLARK**

**EMERGENCY MOTION TO STAY AND FOR RECONSIDERATION  
OF ORDER GRANTING IN PART DEFENDANT'S  
MOTION TO COMPEL TESTIMONY OF DAVID HENRY (DKT. # 178)**

Dr. Barry respectfully requests the Court reconsider aspects of its recent Order Granting in Part Defendant's Motion to Compel, Dkt. # 178. Dr. Barry respectfully contends that portions of the Order are premised on conclusions of fact lacking the necessary evidentiary support in the record and legal conclusions arrived at through the application of aspects of the law of inequitable conduct that were expressly overruled by the Federal Circuit in its *en banc* decision in *Therasense, Inc. v. Becton-Dickson & Co.* "Motions to reconsider serve a very limited purpose: 'to permit a party to correct manifest errors of law or fact, or to present newly discovered evidence.'" *Id.* (quoting *Krim v. pcOrder.com, Inc.*, 212 F.R.D. 329, 331 (W.D. Tex. 2002)). Dr. Barry will show that the findings of implied waiver based on the IMAST Abstract are based on manifest errors of law and fact. Dr. Barry urges the Court to promptly reconsider and correct the Order.<sup>1</sup>

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<sup>1</sup> While Dr. Barry disagrees with the finding of waiver as to the "origin and discovery of the Fig. 6 error," Order at 18, and reserves his right to appeal from that aspect of the Order, Dr. Barry does not seek reconsideration of that ruling.

Dr. Barry also respectfully requests that enforcement of the Order be stayed, if necessary, until the present motion for reconsideration is resolved. Mr. Henry is ordered to testify within the next three weeks. To the extent this Motion for Reconsideration is not resolved before the June 10, 2016 deadline for Mr. Henry's testimony, a stay is appropriate. "It is within the court's discretionary power to stay proceedings in the interest of justice and in control of their dockets." *Andrews v. United States*, No. 4:05-CV-419, 2007 WL 2315964, at \*2 (E.D. Tex. Aug. 10, 2007). For the following reasons, Dr. Barry urges the Court to stay the Order to consider and correct several statements that, if intended to be final conclusions as to those contested issues, would be manifest errors of law and fact.

**I. THE CHARACTERIZATION OF THE IMAST ABSTRACT AS "PRIOR ART" AND "MATERIAL" IS CLEAR LEGAL AND FACTUAL ERROR.**

The Order repeatedly characterizes the IMAST Abstract as "prior art," *see, e.g.* Order at 12, 14-15, but provides no analysis of the relevant evidence, in light of the relevant legal standards, necessary to support that conclusion. To the contrary, the undisputed facts establish that the IMAST Abstract is not prior art, and the statements in the Order to the contrary are manifest error. As with all aspects of its invalidity defense, Medtronic must show by clear and convincing evidence that the IMAST Abstract is in fact prior art. To qualify as "prior art," the IMAST Abstract must have been published more than one year before the patent application was filed. 35 U.S.C. §102(b).<sup>2</sup> The IMAST Abstract was published at the IMAST meeting on July 1, 2004. Barry Decl. ¶¶ 12-14; *IMAST Paper Abstracts, Paper #:109*, ECF No. 49-11 (indicating that IMAST took place from "July 1-3, 2004"). Medtronic does not dispute these facts, and makes no attempt to establish that the IMAST Abstract is "prior art." *See, e.g.*, Defendant's

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<sup>2</sup> The IMAST Abstract was authored by Dr. Barry to describe aspects of his own invention. It therefore cannot predate his invention as required by §102(a).

Motion to Compel, Jan. 29, 2016, ECF No. 131 (referring only to the alleged “21 highly material prior art surgeries”). Because the IMAST Abstract was published less than one year before the December 30, 2004 filing date of the patent application it is not “prior art” as a matter of law. *See Suffolk Technologies, LLC v. AOL Inc.*, 752 F. 3d 1358, 1364 (Fed. Cir. 2014) (“publication” requires clear and convincing evidence that interested persons skilled in the art could find the document after a reasonably diligent search.).

Materiality must also be established by clear and convincing evidence. *Therasense, Inc. v. Beckton Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). The Order does not apply this standard. Rather, it relies on a definition of “materiality” that was expressly overruled in *Therasense*. The Order concludes that the IMAST Abstract is material because it “could establish, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim. 37 C.F.R. §1.56(a).” Order at 14-15. *Therasense* expressly rejected this standard of materiality. 649 F.3d at 1294 (“We do not adopt the standard of materiality set out in PTO Rule 56 [37 C.F.R. §1.56]”). The characterization of the IMAST Abstract as “material” prior art using the incorrect standard is therefore a manifest error. To be material, the prior art reference must establish that the patent claims are unpatentable. *Id.* Because the IMAST Abstract is not prior art it cannot be “but-for material” prior art. Disclosure of that publication would have had no effect on issuance of the ‘358 patent claims. And because it is neither material nor prior art, there was no duty on the part of either Dr. Barry or Mr. Henry to disclose that document to the Patent Office.

Moreover, the IMAST Abstract does not clearly indicate on its face that Dr. Barry performed any surgeries before the critical date, much less surgeries that practiced the methods of any patent claim. New evidence -- the testimony at Medtronic’s own expert given the day

after the Court's Order was served -- establishes as much. The IMAST Abstract describes in general Dr. Barry's surgical technique that "evolved" over time with the development of "linked multiple derotation levers." *IMAST Paper Abstracts, Paper #:109*, ECF No. 49-11. While it goes on to state that a "review of a series of 21 consecutive patients with deformity was done," it does not say when those surgeries took place. *Id.* In fact Medtronic knows well that several of those "21" surgeries took place in 2004 – ***after the critical date.*** Machleidt Decl., Ex. A, Dr. Barry Feb. 24, 2016 Dep., 183:14-187:1; Machleidt Decl., Ex. B, Dr. Barry Feb. 24, 2016 Dep., Ex. 13. More importantly, nowhere does the IMAST Abstract state that any one of the surgeries, much less all "21," included all of the steps of any patent claim. Medtronic's own expert witness on this subject admitted as much in his deposition last week:

Q. And is it your -- from reading [the IMAST Abstract], you understand that that exact technique was used in all 21 consecutive patients with deformity?

A. ***It does not specifically say that,*** but as it's written, one would assume that's what this means, but he doesn't say that it was used on every single case, as far as I can see.

Machleidt Decl., Ex. C, Dr. O'Brien Dep., 154:6-12 (emphasis added). Dr. O'Brien was then pointed to the statement that premised the entire discussion of Dr. Barry's technique and the 21 surgeries: that the technique and tools described "evolved" over time. Considering the IMAST Abstract as a whole, Dr. O'Brien admitted one of ordinary skill in the art reading the IMAST Abstract would understand that the method described – and later claimed in the '358 patent – was not the same technique used for all 21 surgeries:

Q. And the second sentence of the abstract says, "This technique evolved with a design of multiple derotation levers -- of linked multiple derotation levers mounted on a cluster of fixed head screws."

A. I see that.

Q. What did the word "evolved" mean to you in -- in that sentence?

A. It sounds as though the technique changed from beginning to end. But I would assume from evolved – it's not clear if it's the technique that's evolving or the hardware that's evolving. Something changed.

Machleidt Decl., Ex. C, Dr. O'Brien Dep., 154:13-23. In light of this testimony by its own witness, Medtronic cannot meet the burden of showing by *clear and convincing evidence* that the IMAST Abstract, itself not prior art, somehow on its face proves the existence of other prior material.

The reasonable import of the IMAST Abstract is therefore that the technique and tools evolved over the 21 surgeries. No particular surgery, much less all 21 surgeries, are “described in the IMAST Abstract” as to the date of the surgery or the technique employed. The disclosure of the IMAST Abstract therefore cannot alone provide clear and convincing evidence that any of the 21 surgeries were performed using the method Dr. Barry ultimately claimed in the '358 patent. The statement in the Order that the “prior art surgeries described in the IMAST Abstract, alone or in combination, practice all the limitations of the invention,” is therefore manifest error. Because these clear factual errors appear to inform the findings of implied waiver, Dr. Barry respectfully requests reconsideration of the Order. Order at 14.

## **II. THE FINDING OF WAIVER AS TO MR. HENRY'S KNOWLEDGE OF THE “PRIOR ART” SURGERIES IS CLEARLY ERRONEOUS.**

The Court's finding that Dr. Barry is impermissibly using the privilege as a shield to prevent discovery into the “extent to which the prior art surgeries practice the invention,” Order at 17, also requires clarification. Medtronic is well-aware of undisputed evidence that Dr. Barry did not have working derotators capable of performing the claimed methods until July 31, 2003, *after he obtained his first prototype instruments that same day*. Machleidt Decl., Ex. A, Dr. Barry Feb. 24, 2016 Dep., 187:6-9; Machleidt Decl., Ex. D, Dr. Barry Feb. 25, 2016 Dep., 12:14-14:22; Ex. J (July 31, 2003 machine shop receipt). On that day, Dr. Barry may have performed

one of the “21” surgeries using his prototype tools. *Id.* He has testified that he performed three confidential surgeries in August and October 2003 to test and evaluate the prototypes before the critical date. The claimed methods could not have been practiced in any of the 13 surgeries before July 31, 2003, as Dr. Barry did not have the necessary linked derotation tools. At the time Dr. Barry performed these pre-critical date surgeries, Mr. Henry was not aware of Dr. Barry’s existence, much less details of his medical practice. Mr. Henry therefore has no personal knowledge regarding those surgeries. It cannot be that any relevant facts are being “shielded” by Dr. Barry’s assertion of the attorney-client privilege. Rather, as the Court recognizes, Dr. Barry has provided full and forthright testimony on that subject. Order at 17 (“Dr. Barry has testified about the extent to which the prior art surgeries practice the invention.”) Dr. Barry has produced all records in his possession concerning those surgeries. Medtronic has obtained documents and taken the deposition of every other person who could possibly have personal knowledge of the relevant facts. Machleidt Decl., ¶11 (explaining that Medtronic has deposed Dr. Barry and his primary surgical team from the relevant time period). On the other hand, the Order cites no evidence that Mr. Henry ever learned about any of the relevant surgeries while preparing and prosecuting the ’358 patent application. As such, there is no basis on the record to conclude that Dr. Barry is “shielding” evidence on this topic by exercising his right to assert the attorney-client privilege. An application of the doctrine of implied waiver to conclude that Dr. Barry’s communications with his patent lawyer a year or more after he performed these surgeries on the unsupported supposition that these communications would reveal admissible evidence about the surgeries is therefore clearly erroneous.

Similarly, the Court’s reliance on the discussion of whether or not Dr. Barry could file *an international patent application* based on Dr. Barry’s disclosure of the patented technique well

within the grace period, does not imply a waiver on the very different subject of surgeries before the critical date. Mr. Henry advised Dr. Barry that his public disclosure at either the July 1-3, 2004 IMAST meeting in Bermuda, or the December 1-3 2004 2d Annual Pediatric Orthopedic Symposium in Orlando Florida, both before an application could be filed, would preclude a patent under most international patent law. Order at 19-20. That disclosure, well within the one-year grace period in U.S. patent law, does not implicate any disclosure or discussion of surgeries that took place in 2003. Dr. Barry was advised that international patents were precluded. Dr. Barry admits that he has waived privilege on the discussion of his first public disclosure of the inventions and whether or not he could apply for patents outside the United States. There is simply no connection between that waiver as to a public disclosure within the grace period, and the scope of waiver as to any possible knowledge by Mr. Henry of surgeries occurring before the critical date.

Finally, the statement in the Order that Dr. Barry “has not provided dates of the last 13 surgeries that he performed between June of 2003 through June of 2004,” Order at 21, is contrary to the undisputed record. Dr. Barry has disclosed every such surgery, including every document he has concerning those surgeries. He has been deposed and given all of his present recollection about those surgeries. Medtronic has prepared a chart setting forth the date and other facts related to those surgeries, which cites to Dr. Barry’s documents. Machleidt Decl., Ex. B, Dr. Barry Feb. 24, 2016 Dep., Ex. 13. Medtronic has taken the depositions of everyone likely to have been present during those surgeries, and asked all but one of them specifically about the surgeries listed on its summary. Machleidt Decl., Ex. E (Dr. Yvonne Barry Tr. at 61:23-65:9); Ex. F (Ricky Booher Tr. at 66:22-70:19); Ex. G (Janice Munro Tr. at 102:21-108:6); Ex. H (Dr. Stephanie Davidson Tr. at 81:2-83:1) and Ex. I (Francis Franklin Tr. at 84:21-93:4). To the

extent this misperception that Dr. Barry has not provided complete discovery of all known facts about these surgeries informs the finding of waiver, Dr. Barry is entitled to reconsideration.

### **III. THE FINDING OF A “DUTY TO INVESTIGATE” IS PREMISED ON INEQUITABLE CONDUCT LAW THAT HAS BEEN OVERRULED.**

The Order’s finding of a waiver of the attorney-client privilege as to Mr. Henry’s mental impressions and communications with his client regarding the materiality of the IMAST Abstract based on a “duty to investigate” is also clear legal error. Order at 13-15. Citing *Brasseler, U.S.A. I, L.P v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001), the Order premised that finding on Mr. Henry’s supposed “duty to investigate” facts Medtronic contends are apparent from the IMAST Abstract. Order at 15 (“failure to act on this duty [to investigate] can serve as a basis for finding inequitable conduct”). However, the “duty to investigate” as expressed in *Brasseler*, and the rationale for that holding, were expressly overruled by the Federal Circuit in its *en banc* decision in *Therasense*. In *Brasseler* the court found these were a “duty to investigate” because gross negligence was then sufficient to show deceptive intent:

Where an applicant knows of information the materiality of which may so readily be determined, he or she cannot intentionally avoid learning of its materiality, ***even through gross negligence***; in such cases the district court may find that the applicant should have known of the materiality of the information.

267 F.3d at 1380 (citations omitted) (emphasis added). There can be no doubt that *Brasseler* is no longer good law in light of *Therasense*:

A finding that the misrepresentation or omission amounts to gross negligence or negligence under a “should have known” standard does not satisfy this intent requirement. *Kingsdown*, 863 F.2d at 876. “In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.” *Molins*, 48 F.3d at 1181 (emphases added). In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.



*Therasense*, 649 F.3d at 1290 (emphasis in original). In other words, the “duty to investigate” cannot stand in for either actual knowledge of the reference or actual knowledge of its materiality. Both must be shown by clear and convincing evidence. Here, there is no evidence whatsoever that Mr. Henry even knew of the IMAST Abstract while prosecuting the patents. Henry Dep., 127:3-6, June 10, 2015, ECF No. 125-4 (“Q. Did Dr. Barry provide you with a copy of the IMAST Abstract in 2004? A. I don’t recall if he did. I have no recollection of him providing that.”). Even if he had known of the IMAST reference, there can be no waiver of the attorney client privilege so that Medtronic may investigate whether Mr. Henry failed to investigate any aspect of that reference, particularly when it is not itself prior art and does not clearly indicate the likely existence of other possible prior art. The Order finding otherwise, based on an incorrect legal standard, is manifest error. Because the ruling compelling answers to Questions 1, 4, 11, 12, 14, 15, and 16 is based at least in part on Mr. Henry’s alleged duty to investigate, *see* Order at 22-27, Dr. Barry respectfully requests that this determination should be reconsidered in light of the appropriate legal standards.

#### **IV. CONCLUSION**

For the foregoing reasons, Dr. Barry respectfully requests reconsideration of these aspects of the Order, and submits that a stay is warranted until that reconsideration is completed.

DATED: May 17, 2016

Respectfully submitted,

By: /s/ Sean P. DeBruine

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a), and as such, this document was served on all counsel who have consented to electronic service. All other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on May 17, 2016. True and correct copies of all sealed documents were promptly served on all counsel of record by email on May 17, 2016.

DATED: May 17, 2016

/s/ Sean P. DeBruine

Sean P. DeBruine